

Standards for Tissue Banks (In addition to Section 59A-1.005)

(32) Each tissue bank shall comply with 21 CFR Parts 16 and 1270, 1993 and make the records relating to the federal standards available to surveyors for the AHCA.

(33) Organizational staff requirements.

(a) Qualifications of technical personnel vary by nature of responsibility. Qualifications may be demonstrated by certification or by examination administered by the American Association of Tissue Banks for a certified tissue banking specialist.

(b) All supervisory or senior technical personnel shall be certified in tissue banking by a recognized organization (e.g., the American Association of Tissue Banks).

(34) Donor selection.

(a) A medical history shall be examined, if available. If scant medical history is available, as in the case of a sudden death, a documented attempt shall be made to acquire information beyond what is available before these tissues can be released. In the event that additional information or records cannot be found, the medical director shall determine if these tissues are suitable for release for transplantation and document the release in the donor's medical record.

(b) HIV infections. HIV testing is required under Rule 64D-2.005, F.A.C. Potential donors falling into a high-risk group shall be eliminated from the donor pool. This includes high-risk behavior groups and high-risk ethnic or geographic groups, pursuant to paragraph 59A-1.005(11)(a), F.A.C., and the partners of the above groups, as well as intravenous recreational drug users.

(c) Tissues with evidence of infectious diseases are conditions which shall preclude distribution for transplantation. The following is a list of examples of commonly encountered conditions which preclude donation of tissues:

1. Infectious diseases such as:

- a. Septicemia (demonstrable) at time of death;
- b. Systemic mycoses;
- c. Meningitis or encephalitis;
- d. Active systemic viral disease or past history of chronic viral disease;
- e. Active tuberculosis or history of tuberculosis;
- f. Active hepatitis; and
- g. Active syphilis or anatomically demonstrable syphilitic lesions.

2. Bacterial infections such as:

- a. Pyelonephritis;
- b. Peritonitis;
- c. Pneumonia (other than non-confluent bronchopneumonia);
- d. Bacterial endocarditis;
- e. Osteomyelitis; and
- f. Other potential transmittable bacterial diseases.

3. Malignancies. Individuals with malignancies arising anywhere in the body shall be excluded from the donor pool. Any exceptions shall be approved by the medical director.

4. Collagen and immune complex diseases such as:

- a. Rheumatoid arthritis;
- b. Systemic lupus erythematosus;
- c. Polyarteritis nodosa;
- d. Sarcoidosis;
- e. Myasthenia gravis; and
- f. Acute rheumatic fever.

5. Severe trauma. Patients who have a tracheotomy or have been on a respirator for over 96 hours and have evidence of infection, multiple open wounds, or wounds to the abdomen are excluded from the donor pool.

6. Transfused donor.

a. Tissues from a donor who has been transfused shall comply with the FDA Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference.

b. The decision as to whether or not an individual who received a blood transfusion(s) six months or less before death should serve as a tissue donor is a medical judgment. Therefore, the responsibility of accepting tissue from transfused donors rests with the medical director or physician designee. In making such a decision, factors such as information obtained on retesting of blood donors, testing of organ donor recipients, etc., shall be taken into account.

7. A potential donor who has chronic blood transfusions shall be eliminated from the donor pool.

8. Recipients of organ transplants. Recipients of organ transplants shall not be eliminated because of the transplant per se, but must be carefully evaluated because of the drug therapy they receive and the disease processes they might have.

9. Therapeutic drugs. Donors receiving chronic corticosteroid drugs shall be eliminated as bone donors because of the effect on bone. Other drugs in therapeutic doses, which might reside in the tissues, may eliminate the donor from the donor pool. Discoloration of bone with tetracycline does not constitute a reason for eliminating a donor.

10. Other. Toxic exposure sufficient to affect tissue procured and an unknown but suspicious medical history shall constitute a reason for rejecting a donor.

(35) Required studies of the tissue donor in addition to FDA requirements specified in Rule 59A-1.005, F.A.C.

(a) Serologies:

1. HBcAb;

2. FDA-licensed HTLV test;

3. Serologic test for syphilis (STS) – confirmed. Tissues from donors with positive (confirmed) tests shall not be used for transplantation; and

4. Rh determination shall be provided cautioning about the possibility of sensitization.

(b) Evaluation of the donor. Prior to transplantation, the medical director, designees, or medical contractee shall state in writing that the current medical history, postmortem examination and laboratory test results, together with the available previous medical history, are sufficient to indicate that the donor is acceptable for tissue donation.

(36) Microbiological examination. Each tissue bank shall have microbiological laboratory policies and procedures which ensure allograft safety. Documentation of adherence to these policies and procedures is required.

(37) Autopsy. A gross external and, if applicable, internal examination of any area of the donor altered by the retrieval shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the removal of tissues from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain a notation of normal conditions as well as all itemization of all abnormal pathological findings found during the gross examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the tissue bank shall obtain a full medical autopsy by other means. The tissue bank shall affix a copy of the autopsy report to the donor record. The medical director or designees may exercise a waiver of an autopsy on a case-by-case basis and shall justify and document that waiver in the donor's medical record.

(38) Records.

(a) Responses from transplant centers which identify adverse reactions attributable to allografts shall be maintained. The records of the tissue banks shall be open to inspection by the AHCA at a mutually convenient time.

(b) Records shall show the expiration date assigned to specific processed tissues as defined in the agency's policies and procedures.

(c) To ensure suitability of donated tissues for transplantation, records shall be made concurrently with the performance of each step of processing of tissue allografts. Distribution records shall be available but these may be collected and stored separately. All records shall be legible and indelible, shall identify the person or persons performing the procedures, and shall include the dates of written entry. All records shall be made available to that surgeon on request. The only exception is information infringing upon donor confidentiality. All records shall be maintained for a minimum of ten years.

(d) A tissue bank, when sending tissue to a hospital or surgeon, must request in writing that the transplanting surgeon report allograft-related complications to the tissue bank's medical director. Records of adverse reactions and all related follow-up documentation shall be maintained for a period of ten years.

(e) Inventory. A record of all unprocessed, processed, and distributed tissues shall be maintained.

(39) Documentation of donor information. The records shall include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, and related material. The records of the permission to procure the tissue are kept permanently. A final summary statement is written by the physician responsible for the quality assurance of the allografts which he or she has made available to the transplant surgeon.

(40) Timely procurement. The time limitation for tissue retrieval shall be 24 hours if the cadaver is refrigerated and 15 hours if the cadaver is unrefrigerated.

(41) Facilities and equipment.

(a) If the tissue bank has an operating room it shall be reserved for the retrieval of cadaveric tissue on a 24-hour basis. Such an operating room shall conform to standard operating room requirements under Chapter 59A-3, F.A.C. It shall have air filtration, stainless steel furniture, washable walls, etc. Ultraviolet lights and bacterial filters may be utilized to reduce the ambient bacterial flora.

(b) Environmental monitoring procedures shall be established and periodic sampling of air, drains, surfaces, and water faucets shall be documented.

(42) Retrieval and processing procedures.

(a) Tissues shall be retrieved using either aseptic or clean, nonsterile techniques. If tissues are retrieved using aseptic techniques, methods shall be consistent with standard operating room practice. Aseptic technique does not necessarily preclude the need for subsequent tissue sterilization. Allografts procured using aseptic or clean, nonsterile techniques are suitable for transplantation if adequate precautions are taken to identify and eliminate microorganisms.

(b) Tissue banks employing ethylene oxide (ETO) for sterilization of tissues, chambers of freeze-dryers, instruments or equipment must monitor occupational exposure to ethylene oxide. Semi-annual reports of ETO monitoring must be kept for 30 years. Specifically the following requirements must be met and documented:

1. Air change rate – minimum rate for rooms where ethylene oxide is used is 10 air changes per hour.
2. Review of gas circuits. The following must be checked for leaks:
 - a. Gas tank valves;
 - b. Gas tank manifolds including filter cartridges;
 - c. Sterilizer and other equipment door seals;
 - d. Pressure relief valves;
 - e. Gas-steam mixing chambers;
 - f. All elbows, compression fittings, gauges, valves, etc. along the gas circuit;
 - g. Gas inlet into chamber; and
 - h. Chamber air intake filter.
3. ETO alarm must be installed near equipment where ETO spill may be possible.
4. Automatic aeration after sterilization without having to open sterilizer door must be provided.
5. Periodic personnel exposure monitoring must be conducted.
6. A canister type respirator (NIOSH approved and rated for 5,000 ppm ETO) and gloves must be kept in the gas sterilization area in case of an emergency.
7. Material safety data sheets must be kept in the tissue bank and the location of these sheets and content must be known to the employee.
8. An emergency evacuation plan must be posted for all employees to see.
9. Personnel must be trained regarding the safe use of ETO and records retained in the file.
10. All exhaust systems must be non-circulating.

(c) Tissues shall be processed into specimens appropriate for clinical use. The specific methods employed may vary with each type of tissue and with the manner in which it has been procured, but each type of tissue shall be prepared according to written tissue bank procedures.

(d) Sterile bone and tissue allografts shall be packaged in minimum room class 1000 environments. Certification of conformance, issued by outside agencies, must attest that the room meets cleanliness requirements for class 1000 or less of FED-STD-209D. Such certification must be obtained every 12 months. If processing is performed in laminar flow hoods, and not in clean rooms, the latter must be similarly certified every 12 months. Adequate supplies must be available, and there must be adequate space for equipment.

(43) Labeling.

(a) Visual inspection. A sufficient area of the container shall remain unobstructed when the label has been affixed to the container to permit inspection of the contents of freeze dried tissue allografts. Tissues that are vacuum sealed shall be spark tested prior to disposition.

(b) Container label. Containers shall be labeled so as to identify the following:

1. Name of the product;
2. Name and address of the tissue bank;
3. Tissue identification number; and
4. Expiration date, if applicable.

(c) Shipping label. Packages shall be labeled so as to identify the following:

1. Identification of human tissue;
2. Name and address of tissue bank;
3. Name of facility to which tissue is being shipped;
4. Recommended storage temperature; and
5. Special instructions indicated by the particular product, e.g., DO NOT FREEZE.

(44) Shipping.

(a) Shipping shall maintain sterility of the contents and maintain integrity of the appropriate container.

(b) Package insert. All tissues shall be accompanied by a package insert which contains instructions for proper storage and reconstituting when appropriate. Specific instructions shall be enclosed with tissues requiring special handling. Such instructions shall include:

1. Presence of known sensitizing substances;
2. Type and estimated amount of antibiotics added during processing;
3. Source of the tissue (when it is a factor in safe administration);
4. All donor test results and laboratory procedures (including an autopsy, if performed);
5. Secondary sterilization procedure, if utilized;
6. Any chemical agent that may cause a change; and
7. All preservation and the concentration of the preservation used in the processing of tissue allografts, if utilized.

(45) Tissue tracking.

(a) Each tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique tissue identification number which shall serve as a lot number to identify the material during all steps from retrieval through distribution and utilization. Donor number and lot number shall be the same.